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March 19, 2021

By ECF
The Honorable Freda L. Wolfson, Chief, U.S.D.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: *In Re: Fosamax Products Liability Litigation*
Civil Action No. 08-08 (FLW)(LHG)

Dear Judge Wolfson:

Together with our co-counsel, this firm is liaison counsel for Plaintiffs. We write in response to the supplemental authority letter (Doc. 4526) filed by Merck Sharp & Dohme Corp. ("Merck"). For the reasons explained in Plaintiffs' brief opposing preemption (Doc. 4485), Merck cannot satisfy the requirements for preemption set forth by the Supreme Court in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). The Southern District of California's opinion in *In re Incretin-Based Therapies Products Liability Litigation*, No. 13-md-2452, 2021 WL 880316 (S.D. Cal. Mar. 9, 2021), is distinguishable and does not change the analysis.

Incretin-Based Therapies held that the drug manufacturers could not use the CBE regulation to add a warning of pancreatic cancer to the label of incretin drugs because the court concluded there was no "newly acquired information" to justify such a change. *Id.* at *13-14. *Incretin-Based Therapies* acknowledged that this case was "distinguishable" because here, it is undisputed that newly acquired information existed tying Fosamax to atypical femoral fractures. *Id.* at *4. In dicta that the court recognized was "unnecessary," the court also found that clear evidence existed that the FDA would not approve a pancreatic cancer warning. *Id.* at *14. The *Incretin-Based Therapies* court concluded that the FDA had formally rejected a pancreatic cancer warning and has continued to approve new incretin-based drugs without a pancreatic cancer warning. *Id.* at *16-17.

Here, as explained in Plaintiffs' brief opposing preemption, Doc. 4485, at 16-27, the FDA never rejected a warning of atypical femoral fractures, and in fact mandated a warning more than a decade ago. As the Supreme Court explained, the FDA only rejected "Merck's proposal to warn of a risk of 'stress fractures' . . . because '[i]dentification of 'stress fractures' may not be clearly related to the atypical subtrochanteric fractures that have been reported in the literature."

Albrecht, 139 S. Ct. at 1674. The FDA's former Principal Deputy Commissioner, who oversaw drug labeling during the relevant period, explained in a declaration and amicus brief: "FDA

rejected Merck's request to add a Warning about stress fractures. It could not and did not reject a warning regarding AFFs, because Merck had never asked for one. Nothing in the Complete Response Letter supports what Merck . . . contend[s] was the reason behind FDA's decision: a finding by FDA that there was a lack of scientific evidence that Fosamax caused atypical femoral fractures." Doc. 4485-26, Sharfstein Br. 12. The court's conclusion in *Incretin-Based Therapies* that the FDA rejected a pancreatic cancer warning in a variety of ways thus has no bearing here.

In any event, *Incretin-Based Technologies* is a district court opinion that is not binding precedent even in its own district, let alone in this District. *See Camreta v. Greene*, 563 U.S. 692, 709 n.7 (2011). Plaintiffs understand that the plaintiffs in *Incretin-Based Therapies* intend to appeal the district court's ruling and believe that it suffers from numerous factual misstatements and legal errors. For example, *Incretin-Based Technologies* adopted the statement in Justice Alito's opinion in *Albrecht* that FDA "inaction" can support preemption, 2021 WL 880316, at *16, even though the Supreme Court held, contrary to Justice Alito's opinion, that preemption requires FDA "action" that "prohibited" an adequate warning that would comply with state law. *Albrecht*, 139 S. Ct. at 1678.

Respectfully submitted,

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OLSTEIN, BRODY & AGNELLO

/s/ James E. Cecchi

JAMES E. CECCHI

JEC:neh